

**SOP Title:** Siliconization of Aluminum Seals  
**SOP Number:** 15121  
**Revision:** 04

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#### 1. PURPOSE

This procedure describes the proper method of siliconization of aluminum seals using the DCI Washer (BDP MEF 62090).

#### 2. SCOPE

This SOP applies to siliconization of aluminum seals to be used in the filling process performed in ATRF.

**NOTE:** Precautions must be taken to avoid being burned by hot WFI when operating this equipment. Operators must wear latex gloves when handling crimps in order to prevent contaminating them during siliconization.

#### 3. RESPONSIBILITIES

- 3.1 The Director, Technical Operations, Late Process Sciences, Biopharmaceutical Development Program (BDP).
  - Defines this procedure.
- 3.2 BDP manufacturing personnel.
  - Performs the procedure.
- 3.3 The Manager, Formulation and Filling, BDP
  - Ensures that BDP manufacturing personnel are trained in this procedure.
- 3.4 Biopharmaceutical Quality Assurance (BQA).
  - Provides Quality oversight.

## BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

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### 4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
10250	35% Dimethicone Emulsion	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
N/A	Filtered Compressed Air	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
N/A	Water for Injection.	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

### 5. PROCEDURE

#### 5.1 Siliconization of Aluminum Seals.

- 5.1.1 Close the drain valve on the underside of the washer.
- 5.1.2 Place the crimps in the wash basket. Do not fill the basket more than half full with aluminum seals.
- 5.1.3 Fill the washer with WFI to within approximately one inch of the perforated holes on the side of the basket (approximately 70 L).
- 5.1.4 Add 30 mL of the 35% Dimethicone Emulsion.
- 5.1.5 Replace the inner basket lid, ensuring that it is locked in place.
- 5.1.6 Open the air supply valve to create a rolling/boiling action of the contents within the basket. (Pressure will be 5 - 10 psig, depending on how full the basket is).
- 5.1.7 Continue for one minute.
- 5.1.8 At the conclusion of the one minute, close the air supply valve.
- 5.1.9 Open the drain valve on the underside of the washer. Completely drain the water from the washer.
- 5.1.10 Place the aluminum seals on the trays and put the trays into a BSC to assist in drying.

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5.1.11 Double package the aluminum seals in quantities of 1,000 each per autoclave pouches.

### 6. DOCUMENTATION AND RECORDS

Documentation of siliconization of aluminum seal is captured on Form 15105-03, Crimp/Seal Preparation per SOP 15105, Preparation of Vials, Stoppers, and Crimps for CGMP Filling of Final Product.

### 7. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
15105	Preparation of Vials, Stoppers, and Crimps for CGMP Filling of Final Product
15105-03	Crimp/Seal Preparation